DETAILED ACTION

1. The notice of abandonment mailed on 9/16/2010 is herein rescinded as Applicant timely filed a response on 9/3/2010. Examiner thanks Sarah Lhymn for pointing this out in a telephonic communication on 9/16/2010. The response filed on 9/3/2010 has been entered and is herein considered.

Election/Restrictions

2. Applicant's election of the species: coil polymeric block structure: propylene oxide; rod polymeric block structure: poly(L-glutamic acid); copolymer configuration: rod-block-coil di-block in the reply filed on 12/7/10 was previously acknowledged. Upon search, other species encompassed by the instant claims were found and are herein examined for the sake of compact prosecution.

Status of the claims

3. Claims 1-35, 38 were previously pending in the application. Claims 3-6, 10-11, 33-35 and 38 have now been cancelled. Claims 1, 2, 7, 8, 9, 12, 13, 14, 15, 24, 25, 29, 30, 31, 32 have been amended. Claims 39-41 are new claims. Claims 1-2, 7-9, 12-32, 39-41 are now pending and are presented for examination on the merits.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 3 and 6 were rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 3 and 6 have been cancelled by Applicant. Therefore the rejections are moot.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 1-2, 7-9, 12-18, 25-26, 28-31 are rejected under 35 U.S.C. 102(b) as being anticipated by Thunemann et al. (Macromolecules, 2000).

Thunemann et al. disclose a composition comprising at least one rod-coil type block copolymer comprising at least one polymeric coil-block structure of variable conformation (i.e., PEG, polyethylene oxide which reads upon a polyether of the ethylene polyoxide type and derivatives thereof) bonded to at least one rod-block structure of restricted conformation (i.e., PLL, poly-L-lysine), which reads upon a derivative of poly-(L-leucine), poly(L-valine), poly(phenylalanine), poly(L-glutamic acid); polyglutamine, poly(N-benzyloxycarbonyl-L-lysine and gamma-benzyl-L-glutamate, etc. Please note that the instant disclosure does not provide a definition for derivatives and clearly a given poly-amino acid such as poly-L-lysine may be obtained from (i.e., derived from) other poly amino acids.

Thunemann et al. further teaches the composition wherein:

the rod-block structure is of polymeric nature and is constituted in full, or in part, by peptide motifs having free hydrogen atoms with some or all of the free hydrogen

atoms of the peptide motifs participating in non-covalent hydrogen bonds within the rod-block structure,

wherein the rod-coil type copolymer is provided in a physiologically acceptable medium (water, retinoic acid).

Thunemann et al. teach that complexes of polyethylene oxide -*b*- poly(L-lysine) block copolymers with retinoic acid with short poly(L-lysine) segments of 18-30 monomers form core shell micelles. This effective stabilization of the alpha-helix structure seems to be due to the formation of a protective surrounding coat of retinoate and a shell of poly(ethylene oxide). Vitamin A and its analogues, in particular retinoic acid, are involved in the proliferation and differentiation of epithelial tissues and have continued to be used in the treatment of dermatological disorders such as acne, psoriasis and hyperkeratosis (e.g., p. 5908) and therefore is cosmetically compatible (i.e., reads upon cosmetic). The composition of Thunemann et al. is considered useful in the development of drug delivery formulations (e.g., abstract). The limitations drawn to the formulaic conventions of claims 2 and 9 would be inherent to the compositions of Thunemann et al. since they anticipate the structural limitations of said claims. "[T]he discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer." (see MPEP 2112). Thunemann et al. teach aqueous solutions comprising 0.5-5 % w/w (of the rod-block structures (e.g., p. 5909). For complex formation 0.1 g of retinoic acid was dissolved in 40 mL of water at pH 9. One equivalent of PEO-PLL18 and PEO-PLL30 were each dissolved in 15 mL of water (pH

9.0). The samples were prepared by letting droplets of diluted aqueous solutions (0.01% w/w) dry on fresh cleaved muscovite mica surfaces at room temperature. Please note that retinoic acid reads upon a fatty phase as it contains a large non-polar component and that micelles are inherent to emulsions. Further, retinoic acid reads upon a particulate filler and/or pigment. The number average molecular mass of the rod blocks was determined as follows: MW of lysine is 146, PLL18 is about 2322 g/mol, calculated 146x18-18x17 to account for the polymerization water. The number average molecular mass for PEO is 5000 g/mol, therefore the weight ratio of the rod block is 31% relative to the total weight of the copolymer. The copolymer overall number average molecular weight would be 7322 g/mol. The retinoic acid (i.e., a pigment) added (0.1 g) dissolved in 40 mL of water (~40 g) to one equivalent of PEO-PLL18 (97.3 mg) reads upon a particulate phase in an amount of 0.01% to 40% by weight relative to a total weight of the composition (0.1g/ (40+97.3)*100 = 0.07%) (e.g., page 5907, col. 2).

With regards to the limitations "wherein the composition is in the form of a makeup and/or a care product for the skin and/or the lips", "wherein the composition is in the form of a product that has been cast as a stick or a cake" and "the composition is in the form of a care product and/or a makeup for the nails", etc.. MPEP 2111.04 states "Claim scope is not limited by claim language that suggests or makes optional but does not require steps to be performed, or by claim language that does not limit a claim to a particular structure. However, examples of claim language, although not exhaustive, that may raise a question as to the limiting effect of the language in a claim are:

(A) " adapted to " or "adapted for " clauses;

(B) " wherein " clauses; and

(C) " whereby " clauses.

The determination of whether each of these clauses is a limitation in a claim depends on the specific facts of the case." In the instant cases it is not clear as to whether the composition has any structural changes per se that would distinguish from the product taught by Thunemann et al. since it anticipates all the structural limitations set forth in the claims. Furthermore, the claims are drawn to chemical compositions, not to specific products.

With regards to the limitation "cosmetic" which appears in the preamble of the claims, it appears that they do not impart any structural limitation beyond that set forth in the body of the claim. Therefore, since the composition of Thunemann et al. anticipates all the structural limitations set forth in the body of the claim, such preambles are not deemed to introduce a any weight. The determination of whether a preamble limits a claim is made on a case-by-case basis in light of the facts in each case; there is no litmus test defining when a preamble limits the scope of a claim (MPEP 2111.02).

Therefore the reference is deemed to anticipate the instant claims above.

Applicant's arguments

8. Thunemann discloses the results of a study relating to properties of complexes formed by poly(ethylene oxide)-b-poly(L-lysine) (Thunemann, Abstract). More specifically, Thunemann discloses a composition comprising a rod-coil type copolymer having at least one polymeric coil-block structure, such as polyethylene oxide, bonded

to at least one rod-block structure, such as poly(L-lysine) (Thunemann, page 5909, second column). However, Thunemann does not disclose a rod-block structure being a compound selected from the group recited in claims 1 and 32. Thus, Thunemann does not disclose a cosmetic composition comprising at least one rod-coil type block copolymer comprising at least one polymeric coil-block structure of variable conformation bonded to at least one rod-block structure of restricted conformation having the compositional features as recited above in claim 1, and similarly in claim 32.

Based on the above, Thunemann fails to disclose each and every feature of claims 1 and 32 and, thus, does not anticipate claims 1 and 32. The remaining claims variously depend from claim 1 and, likewise, are also not anticipated by Thunemann for at least the reasons set forth above with respect to claim 1, as well as for the additional features recited therein.

Accordingly, reconsideration and withdrawal of the rejection are respectfully requested.

Response to arguments

9. Applicant's arguments have been carefully considered but not deemed persuasive with respect to the composition (i.e., claim 1) for the reasons of record, the reasons set forth above, and for the following reasons: Thunemann et al. disclose a composition comprising at least one rod-coil type block copolymer comprising at least one polymeric coil-block structure of variable conformation (i.e., PEG, polyethylene oxide which reads upon a polyether of the ethylene polyoxide type and derivatives thereof) bonded to at least one rod-block structure of restricted conformation (i.e., PLL,

poly-L-lysine), which reads upon a derivative of poly-(L-leucine), poly(L-valine), poly(phenylalanine), poly(L-glutamic acid); polyglutamine, poly(N-benzyloxycarbonyl-L-lysine and gamma-benzyl-L-glutamate, etc. Please note that the instant disclosure does not provide a definition for derivatives and clearly a given poly-amino acid such as poly-L-lysine may be obtained from (i.e., derived from) other poly amino acids. Other limitations are addressed above.

Therefore the anticipation rejection is maintained with respect to the claims set forth above.

10. Claims 1-2, 9, 14-15, 17, 29-31 are rejected under 35 U.S.C. 102(b) as being anticipated by Kwon et al. (Pharmaceutical Research, 1999).

Kwon et al. teach that soluble block copolymers may self-assemble into novel supramolecular structures, which possess functional properties for drug delivery. These unique molecular architectures are being researched for the delivery of anticancer drugs, proteins and plasmid DNA. A major consideration of these drug delivery systems is their nanoscopic dimensions, which may yield advantages in terms of drug targeting, safety and developments. Moreover, there has been substantial progress in their chemistry, and we can now envision biocompatible, biodegradable synthetic analogues of biological transports systems, lipoproteins or viruses. Some of the block copolymers are: A poly(ethylene oxide)-block-poly(aspartic acid) (PEO-*b*-PAA (e.g., p. 597), PEO-*b*-PLAA (wherein PLAA is a Poly(L) Amino Acid, PEO-*b*-PLL (wherein PLL is poly-L-lysine). The compounds meet the structural limitations of claim 1, including having solubility in water, e.g. p. 597-8 which reads upon a physiologically acceptable medium.

The limitations drawn to the formulaic conventions of claims 2 and 9 would be inherent to the compositions of Kwon et al. since they anticipate the structural limitations of said claims. "[T]he discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer." (see MPEP 2112).

With regards to the limitations "wherein the composition is in the form of a makeup and/or a care product for the skin and/or the lips", "wherein the composition is in the form of a product that has been cast as a stick or a cake" "the composition is in the form of a care product and/or a makeup for the nails", etc. MPEP 2111.04 states "Claim scope is not limited by claim language that suggests or makes optional but does not require steps to be performed, or by claim language that does not limit a claim to a particular structure. However, examples of claim language, although not exhaustive, that may raise a question as to the limiting effect of the language in a claim are:

(A) " adapted to " or "adapted for " clauses;

(B) " wherein " clauses; and

(C) " whereby " clauses.

-to whether the composition has any structural changes per se that would distinguish from the product taught by Kwon et al. since it anticipates all the structural limitations set forth in the claims.

With regards to the limitation "cosmetic" which appears in the preamble of the claims, it appears that they do not impart any structural limitation beyond that set forth in the body of the claim. Therefore, since the composition of Kwon et al. anticipates all the

structural limitations set forth in the body of the claim, such preambles are not deemed to introduce a any weight. The determination of whether a preamble limits a claim is made on a case-by-case basis in light of the facts in each case; there is no litmus test defining when a preamble limits the scope of a claim (MPEP 2111.02).

Therefore the reference is deemed to anticipate the instant claims above.

Applicant's arguments

11. Kwon discloses soluble block copolymers such as: A poly(ethylene-oxide)-block-poly(aspartic acid) (PEO-b-PAA), PEO-b-poly(13-benzyl-L-asparate), PEO-b-poly(D,L lactic acid), and PEO-b-poly(L-lysine) (Kwon, pages 597-98). However, Kwon suffers from similar deficiencies as Thunemann with respect to claims 1 and 32. Namely, Kwon does not disclose a rod-block structure being a compound selected from the group, as recited in claims 1 and 32. Thus, Kwon does not disclose a cosmetic composition comprising at least one rod- coil type block copolymer comprising at least one polymeric coil-block structure of variable conformation bonded to at least one rod-block structure of restricted conformation having the compositional features, as recited in claim 1.

Based on the above, Kwon fails to disclose each and every feature of claims 1 and 32 and, thus, does not anticipate claims 1 and 32. The remaining claims variously depend from claim 1 and, likewise, are also not anticipated by the applied reference for at least the reasons set forth above with respect to claim 1, as well as for the additional features recited therein.

Accordingly, reconsideration and withdrawal of the rejection are respectfully requested.

Response to arguments

12. Applicant's arguments have been carefully considered but not deemed persuasive with respect to the composition (i.e., claim 1) for the reasons of record, the reasons set forth above, and for the following reasons: Kwon discloses a composition comprising at least one rod-coil type block copolymer comprising at least one polymeric coil-block structure of variable conformation (i.e., PEG, polyethylene oxide which reads upon a polyether of the ethylene polyoxide type and derivatives thereof) bonded to at least one rod-block structure of restricted conformation [i.e., PAA (poly-aspartic acid), PLL (poly-lysine), etc.], which read upon a *derivative* of poly-(L-leucine), poly(L-valine), poly(phenylalanine), poly(L-glutamic acid); polyglutamine, poly(N-benzyloxycarbonyl-L-lysine and gamma-benzyl-L-glutamate, etc. Please note that the instant disclosure does not provide a definition for the term *derivative* and clearly a given poly-amino acid such as poly-L-lysine may be obtained from (i.e., derived from) other poly amino acids. Other limitations are addressed above.

Therefore the anticipation rejection is maintained with respect to the claims set forth above.

Claim Rejections - 35 USC § 103

13. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

14. Claims 1-2, 9, 14-15, 17, 29-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kwon et al. (Pharmaceutical Research, 1999) in view of Wiley et al. (US 5,470,510).

Kwon et al. is relied upon as above. Kwon et al.'s disclosure includes some block copolymers such as: A poly(ethylene oxide)-block-poly(aspartic acid) (PEO-*b*-PAA (e.g., p. 597), PEO-*b*-PLAA (wherein PLAA is a Poly(L-Amino Acid), PEO-*b*-PLL (wherein PLL is poly-L-lysine) for drug delivery and being soluble in the physiological medium water (e.g., p. 597-8).

Kwon et al. do not expressly teach the poly(L)amino acid being Poly (L-glutamic acid).

Willey et al. teach poly(glutamic acid) may be used to make homopolymers of glutamic acid and block copolymers with biodegradable monomers or polymers such as PEO (e.g., abstract, Col. 2).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to make complexes PEO-*b*-PLAA, wherein PLAA is poly(glutamic acid). One of ordinary skill in the art at the time the invention was made would have been motivated to do in order to make delivery agents taught by 7won to be PEO-*b*-PLAA wherein PLAA could be any amino acid. One of ordinary skill in the art at the time the invention was made would have had a reasonable expectation of success since Willey et al. taught that poly(glutamic acid) could be used to make homopolymers of glutamic acid and block copolymers with biodegradable monomers or polymers such as PEO (e.g., abstract, col. 2).

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

15. Claims 1-2, 9, 14-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kwon et al. (Pharmaceutical Research, 1999) in view of Cooper et al. (WO 95/22991, cited in the IDS dated 6/12/06).

Kwon et al. is relied upon as above. Kwon et al.'s disclosure includes some block copolymers such as: A poly(ethylene oxide)-block-poly(aspartic acid) (PEO-*b*-PAA (e.g., p. 597), PEO-*b*-PLAA (wherein PLAA is a Poly(L) Amino Acid, PEO-*b*-PLL (wherein PLL is poly-L-lysine) for drug delivery and being soluble in the physiological medium water (e.g., pages. 597-8).

Kwon et al. do not expressly teach the PEO being substituted for polypropylene oxide.

Cooper et al. teach linear block copolymer comprising units of an alkylene oxide (including propylene oxide, see page 6), linked to units of peptide via a linking group useful as imaging agent, drug, prodrug or as delivery system. (e.g., pages. 1-10). Also Cooper et al. teach the compositions may have adsorbents such as kaolin and bentonite, fillers or extenders such as starches, sucrose, glucose, mannitol, and silicic acid. Liquid dosage forms may include emulsifiers, other solvents such as oils,

particularly cottonseed oil, groundnut oil, olive oil, castor oil, fatty acid esters, etc. (p. 36). Compositions may include cocoa butter or wax (e.g., page 37).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the compound of Kwon by using polypropylene oxide as taught by Cooper et al. in order to obtain other useful delivery agents. One of ordinary skill in the art at the time the invention was made would have been motivated to do so to make other delivery agents since both Kwon et al. and Cooper et al. teach the same generic parameters of making delivery agents with alkylene oxide and a peptide.

One of ordinary skill in the art at the art the invention was made would have had a reasonable expectation of success since Cooper et al. teaches a wide variety of peptides could be used with the propylene oxide (e.g., pages 7-8).

With regards to the limitations drawn to relative weight of the solid fat in the fatty phase, or the relative weight of the particulate phase, such limitations are not expressly taught. However, "[g]enerally, differences in concentration or temperature will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." (See MPEP 2144.05).

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of

ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Applicant's arguments

16. As background, polymers compounds are frequently used in cosmetic compositions to provide, inter alia, improved formulations, increased durability and added comfort. For example, acrylic polymers are often used in hair styling products to enable hairstyles to hold better. In order for the hair styling product to have a long lasting effect, plasticizers can be added to lower the glass transition temperature. However, this can generate a sticky effect with use of the product and/or decrease its holding power. Similar challenges exist with respect to nail varnishes and other cosmetic products. Thus, there is a need for a cosmetic composition comprising polymers that yield superior results with respect to mechanical strength as well as stickiness (specification, page 1). The claimed cosmetic composition addresses these needs by providing a composition comprising at least one rod-coil type block copolymer comprising at least one polymeric coil-block structure of variable conformation bonded to at least one rod-block structure of restricted conformation, having the compositional features recited in claims 1 and 32.

Applicants' have discovered a synergistic effect resulting from the rod-coil-type block copolymer comprised of the coil-block structure and rod-block structure having the compositional features recited in claims 1 and 32 (specification, page 42-45). As shown in Examples 4-6 of the specification, the claimed rod-coil-type block copolymer yields superior results when used in cosmetic compositions for the hair and nails, particularly

with respect to a sticky effect. These features and benefits are not disclosed in Kwon or Willey, nor do the applied references disclose how to achieve these features, or even that these features could be achieved. The references thus provide no reason or rationale for one of ordinary skill in the art to have combined and modified the references in manner necessary to have obtained the claimed composition with any reasonable expectation of success or improvement, without the benefit of Applicants' specification.

More specifically, Kwon relates to micelle-like structures or nanospheres provided by the self-assembly of block copolymers that may be useful for drug delivery; and Willey is directed to the use of polymers of glutamic acid as a dispersing, soil-suspending or anti- redeposition agent in laundry detergents or cleaning compositions (see Kwon, page 597; and Willey, Abstract and col. 1, lines 1-4).

Further given the unpredictability of how various chemicals will react with one another, it is respectfully asserted that the Office Action must provide some reason or rationale that would have guided one of ordinary skill in the art to have chosen the specific poly(L)amino acid to be poly(L-glutamic acid). This is emphasized by the fact that Kwon's article is directed to a need to research these compositions, with no reason or rationale to have chosen any specific amino acid over another (Kwon, page 597 and page 599, first column). Thus, any assertion that one of ordinary skill in the art at the time of the invention would have somehow modified Kwon in view of Willey to have replaced the poly(L)amino acid with L- glutamic acid, without any reason or rationale in the applied references for such a replacement, is improper hindsight reasoning based

solely on Applicants' disclosure and does not constitute a showing of prima facie obviousness.

Based on the above, Kwon and Willey would not have rendered claims 1 and 32 obvious. The remaining claims variously depend from claim 1 and, likewise, would not have been rendered obvious by the applied references for at least the reasons set forth above with respect to claim 1, as well as for the additional features recited therein. Accordingly, reconsideration and withdrawal of the rejection are respectfully requested.

Response to arguments

17. Applicant's arguments with respect to the composition have been considered and not deemed persuasive for the reasons of record, for the reasons set forth above and for the following reasons: In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See In re McLaughlin, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971). In the instant case, the Kwon reference teach a generic poly amino acid, can be used, in the construction of micelle-like structures or coil-rod type as instantly claimed. The Wiley reference is used to evidence that one of these poly amino acids can be poly glutamic acid. Thus a motivation, i.e., that the Kwon reference is not limited to any specific poly amino acid, is provided and would be evident to one of ordinary skill in the

art that the reference of Kwon is not limited to the specific examples presented. The references Wiley Furthermore, with regards to the unexpected results drawn to stickiness as set forth in Examples 4-6, it is noted that these are not commensurate in scope with the claims. Furthermore, as Applicant states in the response dated 9/3/2010, page 13, "given the unpredictability of how various chemicals will react with one another" the presentation of Examples 4-6, which are drawn polypropylene glycol and poly(L-glutamic acid) or poly(valine) polymers, and are therefore not commensurate in scope with the claims. Thus the rejection is maintained for the claims set forth above.

18. Claims 1-2, 7-9, 12-19, 28-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brzezinska et al. (Macromolecules, 2002; citation 9 in the IDS dated 9/11/2006).

Brzezinska et al. disclose a composition comprising at least one rod-coil type block copolymer comprising at least one polymeric coil-block structure of variable conformation (i.e., PEG, polyethylene oxide which reads upon a polyether of the ethylene polyoxide type and derivatives thereof) bonded to at least one rod-block structure of restricted conformation (i.e., poly(gamma-benzyl-L-glutamate))/

Brzezinska et al. further teaches the composition wherein:

the rod-block structure is of polymeric nature and is constituted in full, or in part, by peptide motifs having free hydrogen atoms with some or all of the free hydrogen atoms of the peptide motifs participating in non-covalent hydrogen bonds within the rod-block structure (e.g. pages 2970-2971).

Brzezinska et al. do not expressly disclose the composition wherein the rod-coil type copolymer is provided in a physiologically acceptable medium.

However, Brzezinska et al. do teach that the polymers made are currently being studied for use in many biomedical applications such as drug and gene delivery where the functionality and potential degradability of the polypeptide segments provide advantages. The pentablock copolymers of Brzezinska et al. possess added capabilities for such applications since extra functionality (e.g., a hydrophobic center domain for drug loading) and potential for more complex self- assembled structures (e.g., multilayered micelles) can be readily engineered into the materials (e.g., page 2975).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to add a physiological medium such as water or oil to the copolymers of Brzezinska et al. One of ordinary skill in the art at the time the invention was made would have been motivated to do so in order to use in many biomedical applications such as drug and gene delivery where the functionality and potential degradability of the polypeptide segments provide advantages (e.g., page 2975). One of ordinary skill in the art at the time the invention was made would have had a reasonable expectation of success since the pentablock copolymers of Brzezinska et al. were disclosed to possess added capabilities for such applications since extra functionality (e.g., a hydrophobic center domain for drug loading) and potential for more complex self- assembled structures (e.g., multilayered micelles) can be readily engineered into the materials (e.g., page 2975).

The limitations drawn to the formulaic conventions of claims 2 and 9 would be inherent to the compositions of Brzezinska et al. since they comprise the structural limitations of said claims. "[T]he discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer." (see MPEP 2112).

With regards to the concentration differences, [g]enerally, differences in concentration or temperature will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." (see MPEP 2144.05).

With regards to the limitations "wherein the composition is in the form of a makeup and/or a care product for the skin and/or the lips", "wherein the composition is in the form of a product that has been cast as a stick or a cake" and "the composition is in the form of a care product and/or a makeup for the nails", etc.. MPEP 2111.04 states "Claim scope is not limited by claim language that suggests or makes optional but does not require steps to be performed, or by claim language that does not limit a claim to a particular structure. However, examples of claim language, although not exhaustive, that may raise a question as to the limiting effect of the language in a claim are:

(A) " adapted to " or "adapted for " clauses;

(B) " wherein " clauses; and

(C) " whereby " clauses.

The determination of whether each of these clauses is a limitation in a claim depends on the specific facts of the case." In the instant cases it is not clear as to whether the composition has any structural changes per se that would distinguish from the product taught by Brzezinska et al. since it comprises all the structural limitations of the copolymer set forth in the claims. Furthermore, the claims are drawn to chemical compositions, not to specific products.

With regards to the limitation "cosmetic" which appears in the preamble of the claims, it appears that they do not impart any structural limitation beyond that set forth in the body of the claim. Therefore, since the composition of Brzezinska et al. comprises all the copolymer structural limitations set forth in the body of the claim, such preambles are not deemed to introduce a any weight. The determination of whether a preamble limits a claim is made on a case-by-case basis in light of the facts in each case; there is no litmus test defining when a preamble limits the scope of a claim (MPEP 2111.02).

Thus, the invention as a whole is prima facie obvious over the references, especially in the absence of evidence to the contrary.

Claim Rejections - 35 USC § 112

19. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

20. Claims 1-2, 7-9, 12-32, 39-41 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to

reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The MPEP states that the purpose of the written description requirement is to ensure that the inventor had possession, as of the filing date of the application, of the specific subject matter later claimed by him. The courts have stated:

> "To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention." Lockwood v. American Airlines, Inc., 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (1997); In re Gosteli, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) (" [T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed."). Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." Lockwood, 107 F.3d at 1572, 41 USPQ2d at 1966." Regents of the University of California v. Eli Lilly & Co., 43 USPQ2d 1398.

The MPEP lists factors that can be used to determine if sufficient evidence of possession has been furnished in the disclosure of the Application. These include "level of skill and knowledge in the art, partial structure, physical and/or chemical properties, functional characteristics alone or coupled with a known or disclosed correlation between structure and function, and the method of making the claimed invention. Disclosure of any combination of such identifying characteristics that distinguish the claimed invention from other materials and would lead one of skill in the art to the conclusion that the applicant was in possession of the claimed species is sufficient." MPEP 2163.

Further, for a broad generic claim, the specification must provide adequate written description to identify the genus of the claim. In Regents of the University of California v. Eli Lilly & Co., the court stated:

"A written description of an invention involving a chemical genus, like a description of a chemical species, 'requires a precise definition, such as by structure, formula, [or] chemical name,' of the claimed subject matter sufficient to distinguish it from other materials. Fiers, 984 F.2d at 1171, 25 USPQ2d at 1606; In re Smythe, 480 F.2d 1376, 1383, 178 USPQ 279, 284-85 (CCPA 1973) ("In other cases, particularly but not necessarily, chemical cases, where there is unpredictability in performance of certain species or subcombinations other than those specifically enumerated, one skilled in the art may be found not to have been placed in possession of a genus. . . ."). Regents of the University of California v. Eli Lilly & Co., 43 USPQ2d 1398.

The MPEP further states that if a biomolecule is described only by a functional characteristic, without any disclosed correlation between function and structure of the sequence, it is "not sufficient characteristic for written description purposes, even when accompanied by a method of obtaining the claimed sequence." MPEP 2163. The MPEP does state that for generic claim the genus can be adequately described if the disclosure presents a sufficient number of representative species that encompass the genus. MPEP 2163. If the genus has a substantial variance, the disclosure must describe a sufficient variety of species to reflect the variation within that genus. See MPEP 2163. Although the MPEP does not define what constitute a sufficient number of representative, the Courts have indicated what do not constitute a representative number species to adequately describe a broad generic. In Gostelli, the Court determined that the disclosure of two chemical compounds within a subgenus did not describe that subgenus. In re Gostelli, 872 F.2d at 1012, 10 USPQ2d at 1618.

In the instant case, the claims are drawn to cosmetic compositions comprising at least one rod-coil type block copolymer comprising at least one polymeric coil-block structure of variable conformation bonded to at least one rod-block structure of restricted conformation, wherein:

the at least one rod-coil type block copolymer is provided in a physiologically acceptable medium; and

the rod-block structure is of polymeric nature and is constituted in full, or in part, by peptide motifs having free hydrogen atoms with some or all of the free hydrogen atoms of the peptide motifs participating in non-covalent hydrogen bonds within the rod-block structure,

the rod-block structure being selected from the group consisting of:

-poly(L-leucine), poly(L-valine), poly(phenylalanine);

-poly(L-glutamic) and salts thereof;

-polyglutamine;

-polypeptide copolymers selected from the group consisting of poly(hydroxyethyl-L-glutamine and leucine), poly(hydroxyethyl-L-glutamine and valine), poly(gamma-benzyl-L-glutamate and leucine), poly(gamma-benzyl-L-glutamate and D,L-phenylalanine), poly(gamma-benzyl-L-glutamate and cinnamylglutamate), poly(N-benzyloxycarbonyl-L-lysine and gamma-benzyl-L-glutamate) and salts thereof; and

-derivatives thereof;

the polymeric coil-block structure being selected from the group consisting of:

-polyethers of the ethylene polyoxide type, propylene polyoxide and copolymers thereof;

-homopolymers of siloxane; and

-copolymers, salts and derivatives thereof.

With regards to the "derivatives thereof" phrase, the instant disclosure does not expressly provide a definition of what a derivative is and/or how to obtain it, e.g., is it obtained by adding, removing or changing atoms in the claimed composition, and what kind of additions, subtractions or changes are included that still retain the rod and/or coil

type conformations. The specification does provide examples of what qualify as compounds of the claimed invention (see, e.g, disclosure, pages 42-45, Examples 1-6), however, these are limited to a few examples rod-coil type block copolymers, limited to: polypropylene glycol- block - poly(L-glutamic acid) polymer; poly(valine) - block - poly(ethylene oxide co propylene oxide –block- poly(valine); poly(benzyl-glutamate) - block - poly(ethylene oxide co propylene oxide –block- poly(benzyl-glutamate) but do not address any derivatives or how to obtain them. It is unquestionable that claims 1 and 32 are broad generic with respect all possible compounds and methods encompassed by the claims. The possible structural variations resulting from a derivative are not limited in any way except for maintaining the rod-coil configuration. It must not be forgotten that the MPEP states that if a biomolecule is described only by a functional characteristic, without any disclosed correlation between function and structure of the sequence, it is "not sufficient characteristic for written description purposes, even when accompanied by a method of obtaining the claimed sequence." MPEP 2163. Here, though the claims may recite some functional characteristics, the claims lack written description because there is no disclosure of a correlation between function and structure of the compounds, specifically the claimed "derivatives" beyond expressly claimed compounds and/or compounds disclosed in the examples in the specification. The description requirement of the patent statute requires a description of an invention, not an indication of a result that one might achieve if one made that invention. See In re Wilder, 736 F.2d 1516, 1521, 222 USPQ 369, 372-73 (Fed. Cir. 1984) (affirming rejection because the specification does "little more than outlin[e] goals appellants hope the claimed invention achieves and the problems the invention will hopefully ameliorate."). Accordingly, it is deemed that the specification fails to provide adequate written description for the genus of the claims as written including *derivatives*

of poly(amino acids) and homopolymers of siloxane and does not reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the entire scope of the claimed invention.

Conclusion

21. No claim is allowed.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

22. Any inquiry concerning this communication or earlier communications from the examiner should be directed to MARCELA M. CORDERO GARCIA whose telephone number is (571)272-2939. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia J. Tsang can be reached on (571) 272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Marcela M Cordero Garcia/
Examiner, Art Unit 1654

MMCG 10/2010